

## REMARKS

Claims 1, 2, 29-33, 45-49, 57-59, 62-64, 70-74, 86-90 and 98-100 are pending in the application. Claims 1, 29, 30, 46-48, 58, 59, 62, 63, 70, 71, 87-89, 99 and 100 are allowed. Claims 2 and 64 are objected to. Claims 31-33, 45, 49, 57, 72-74, 86, 90 and 98 stand rejected under 35 U.S.C. § 102, first paragraph, for lack of written description and/or lack of enablement based on a number of positions laid out in detail in the 09/23/03 Office Action. Applicant respectfully disagrees with the conclusions set forth in that office action. However, in order to expedite prosecution of a portion of their invention of particular current interest, Applicant has presented a set of more narrowly focused amended claims on pages 2-10 of this paper (See also attached Appendix A). Specifically, Applicant has amended claims 31-33, 45, 49, 57, 72-74, 86, 90 and 98, and has canceled claims 2, 64 and 69. Claims 1, 29, 30, 46-48, 58, 59, 62, 63, 70, 71, 87-89, 99 and 100 remain unchanged. Applicant respectfully submits that no new matter is added through the proposed amendment to the claims. Below we address each of the rejections stated in the Office Action as if it were applied to the newly amended claims.

The deletion of any claims and any other loss of claimed subject matter is being made solely to expedite prosecution of the subject matter now claimed, rather than in acquiescence to any positions taken by the Examiner. In fact, Applicant is *not* acquiescing to any of those positions and are submitting their amendments without prejudice to the subsequent prosecution of claims to some or all of the subject matter which might be lost by virtue of this paper. Applicant additionally reserves the right to re-introduce the subject matter of any of the canceled claims, or subject matter which might be lost by virtue of amendments set forth in this paper, in continuing or divisional applications.

### ***Claim Amendments***

Claims 31-33, 45, 49, 57, 72-74, 86, 90 and 98, as amended, no longer recite the language concerning opioid and SP binding moiety *derivatives*.

Applicant respectfully submits that the amendments, as described above and detailed herein, do not present new matter, and Applicant thus respectfully requests consideration of these amendments in the following remarks.

### ***Claim Objections***

A. Applicant intended to cancel claim 69 in the Amendment filed June 18, 2003, but inadvertently omitted to specify the claim status as “canceled”. Applicant hereby cancels claim 69.

B. Claims 2 and 64 are objected to under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 2 and 64 have been canceled, thereby obviating the stated objection.

### ***Rejections under 35 U.S.C. § 112, first paragraph - enablement***

A. Claims 31-33, 45, 49, 57, 72-74, 86, 90 and 98 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and/or use the invention. Specifically, the Examiner has rejected the above-listed claims because they recite “**derivatives**”, and argues that the meaning of the term is not clear enough to enable one skilled in the art to practice the invention.

In an effort to expedite prosecution as to the subject matter of particular current interest to Applicant, and without conceding the correctness of the Examiner’s position, Applicant has amended the claims to remove the language concerning “derivatives”. Applicant explicitly reserves the right to pursue subject matter directed to chimera comprising  $\mu$  opioid and SP receptor binding moiety *derivatives* in Continuing applications.

The stated rejection is now moot.

### ***Rejections under 35 U.S.C. § 112, first paragraph – written description***

A. Claims 31-33, 45, 49, 57, 72-74, 86, 90 and 98 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and/or use the invention. Specifically, the Examiner has rejected the above-listed claims because they recite “**derivatives**”, and argues that the meaning of the term is not clear enough to enable one skilled in the art to practice the invention.

In an effort to expedite prosecution as to the subject matter of particular current interest to Applicant, and without conceding the correctness of the Examiner's position, Applicant has amended the claims to remove the language concerning "derivatives".

The stated rejection is now moot.

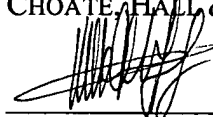
***Rejoinder of Additional SEQ ID NOs***

Applicant greatly appreciates any opportunity the Examiner may be willing to give Applicant to recombine additional SEQ ID NOs. upon allowance of this case.

In view of the foregoing Amendments and Remarks, Applicant respectfully submits that the present case is now in condition for allowance; a Notice to that effect is hereby requested. Applicant would like to thank the Examiner for careful review and consideration of this case and if the Examiner believes that a telephone interview would be of assistance in advancing the prosecution of this application, the Examiner is invited to telephone the undersigned (617) 248-5150.

Please charge any fee that may be required or credit any overpayment to our Deposit Account No.: 03-1721.

Respectfully submitted,  
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- APPENDIX A -

**Claims as Pending After Entrance of the Present Amendment**

1. (Thrice amended) A chimeric peptide comprising an agonist  $\mu$  opioid receptor binding moiety at its N-terminus and an agonist Substance P receptor binding moiety at its C-terminus, wherein said peptide induces analgesia.

Claims 2-28 (Canceled)

- 29 (Once amended) The peptide of claim 1 wherein the N-terminal amino acid residue of said opioid receptor binding moiety is a free amine.
- 30 (Once added) The peptide of claim 29 wherein the N-terminal amino acid residue of said opioid receptor binding moiety is Tyr.
- 31 (Twice amended) The peptide of claim 30 wherein said opioid receptor binding moiety is a peptide having any one of SEQ ID Nos: 1-11, or N-terminal fragment thereof.
- 32 (Thrice amended) The peptide of claim 30 wherein said opioid receptor binding moiety is endomorphin 1, endomorphin 2, or N-terminal fragment thereof.
- 33 (Thrice amended) The peptide of claim 32 wherein said opioid receptor binding moiety is a peptide having SEQ ID No: 2 or 3, or N-terminal fragment thereof.

Claims 34-44 (Canceled)

45. (Four times amended) The peptide of claim 1, wherein said agonist Substance P receptor binding moiety comprises Substance P, or C-terminal Substance P fragment thereof.

46. (Once amended) The peptide of claim 1, wherein the –COOH moiety of the C-terminal amino acid residue of said Substance P receptor binding moiety is protected.
47. The peptide of claim 46 wherein the –COOH moiety of the C-terminal amino acid residue of said Substance P receptor binding moiety is amidated.
48. The peptide of claim 47 wherein the C-terminal amino acid residue of said Substance P receptor binding moiety is Met-NH<sub>2</sub>.
49. (Thrice amended) The peptide of claim 48 wherein said Substance P receptor binding moiety is a peptide having any one of SEQ ID Nos: 21, 36 and 38-41, or C-terminal fragment thereof.

Claims 50-56 (Canceled)

57. (Thrice amended) The peptide of claim 1 wherein the opioid receptor binding moiety is endomorphin 1, endomorphin 2, or N-terminal fragment thereof; and the Substance P receptor binding moiety is Substance P, or C-terminal fragment thereof.
58. The chimeric peptide of claim 1 wherein the peptide has SEQ ID No: 42.
59. The chimeric peptide of claim 1 wherein the peptide has SEQ ID No: 43.

Claims 60-61 (Canceled)

Claim 62 A pharmaceutical composition comprising the peptide of claim 1 and a pharmaceutically acceptable diluent.

Claim 63 The pharmaceutical composition of claim 62, further comprising an adjuvant.

Claims 64-69 (Canceled)

Claim 70 (Twice amended) The pharmaceutical composition of claim 62 wherein the N-terminal amino acid residue of said opioid receptor binding moiety is a free amine.

Claim 71 (Once amended) The pharmaceutical composition of claim 70 wherein the N-terminal amino acid residue of said opioid receptor binding moiety is Tyr.

Claim 72 (Thrice amended) The pharmaceutical composition of claim 71 wherein said opioid receptor binding moiety is a peptide having any one of SEQ ID Nos: 1-11, or N-terminal fragment thereof.

Claim 73 (Thrice amended) The pharmaceutical composition of claim 71 wherein said opioid receptor binding moiety is endomorphin 1, endomorphin 2, or N-terminal fragment thereof.

Claim 74 (Twice amended) The pharmaceutical composition of claim 73 wherein said opioid receptor binding moiety is a peptide having SEQ ID No: 2 or 3, or N-terminal fragment thereof.

Claims 75-85 (Canceled)

Claim 86 (Thrice amended) The pharmaceutical composition of claim 62, wherein said agonist Substance P receptor binding moiety comprises Substance P, or C-terminal Substance P fragment thereof.

Claim 87 (Once amended) The pharmaceutical composition of claim 62, wherein the -COOH moiety of the C-terminal amino acid residue of said Substance P receptor binding moiety is protected.

Claim 88 (Once amended) The pharmaceutical composition of claim 87 wherein the –COOH moiety of the C-terminal amino acid residue of said Substance P receptor binding moiety is amidated.

Claim 89 (Once amended) The pharmaceutical composition of claim 88 wherein the C-terminal amino acid residue of said Substance P receptor binding moiety is Met-NH<sub>2</sub>.

Claim 90 (Thrice amended) The pharmaceutical composition of claim 89 wherein said Substance P receptor binding moiety is a peptide having any one of SEQ ID Nos: 21, 36 and 38-41, or C-terminal fragment thereof.

Claims 91-97 (Canceled)

98. (Twice amended) The pharmaceutical composition of claim 62 wherein the opioid receptor binding moiety is endomorphin 1, endomorphin 2, or N-terminal fragment thereof; and the Substance P receptor binding moiety is Substance P, or C-terminal fragment thereof.

99. (Once amended) The pharmaceutical composition of claim 62 wherein the peptide has SEQ ID No: 42.

100. (Once amended) The pharmaceutical composition of claim 62 wherein the peptide has SEQ ID No: 43.

Claims 101-102 (Canceled)